

I Claim:

1. A device for treatment of obesity of a patient comprising:

an annular element having a relatively large outer boundary and a relatively small inner boundary;

5 an elongated flexible tube extending between a proximal end and a distal end, said tube defining a central lumen within said tube, said proximal end of said tube being connected to said relatively small inner boundary of said annular element, and forming a continuous passageway through a region interior to said relatively small inner boundary and said lumen,

10 wherein said relatively large outer boundary of said annular element is adapted to be attached to an inner wall of a stomach of said patient, such that said annular element divides said stomach into two chambers, an esophagus-end chamber close to an esophagus of said patient, and a pylorus-end chamber close to a pylorus of said patient, and wherein said esophagus-end chamber is in fluid communication with said
15 lumen of said tube.

2. A device according to claim 1, wherein said annular element is flat.

3. A device according to claim 1, wherein said annular element is trumpet-shaped.

4. A device according to claim 1, wherein said annular element is a substantially
20 conical-shaped element extending between a relatively large proximal end at said relatively large outer boundary and a relatively small distal end at said relatively small inner boundary, said conical-shaped element defining a hollow interior region extending between the two ends.

5. A device according to claim 1, wherein said esophagus-end chamber has an
25 enclosed volume of about 30 to 70 ml.

6. A device according to claim 1, wherein said annular element defines an opening at said relatively small boundary, said opening connected to said lumen of said tube, wherein said opening has a diameter of about 0.8 to 1.5 cm.

7. A device according to claim 1, wherein said device further comprises a valve
30 assembly disposed within said passageway near said proximal end of said tube for controlling opening and closing of said passageway.

8. A device according to claim 7, wherein said valve assembly opens when a pressure differential from a proximal side of said valve assembly to a distal side of said valve assembly is greater than a predetermined value, and said valve assembly closes when said pressure differential is less than the predetermined value.

5 9. A device according to claim 8, wherein said predetermined value is approximate to a pressure differential created by swallowing.

10. A device according to claim 8, wherein said predetermined value is about 5 mmHg to 30 mmHg.

10 11. A device according to claim 7, wherein said valve assembly comprises an one-way valve, allowing passage of food from a proximal side to a distal side of said valve and impeding passage of food from the distal side to the proximal side.

12. A device according to claim 7, wherein said valve assembly comprises a circular member attached to said relatively small boundary of said annular element, said circular member defining at least one slit cutting through said circular member, said slit being adapted for passage of food when expanded.

15 13. A device according to claim 7, wherein said valve assembly is characterized by hysteresis such that said valve assembly has an opening pressure differential across said valve assembly and a closing pressure differential across said valve assembly, said opening pressure differential being greater than said closing pressure differential.

20 14. A device according to claim 13, wherein said first predetermined value is a pressure differential created by swallowing.

15. A device according to claim 13, wherein said hysteresis means of said valve assembly comprises:

an elastic hinge element extending from an inner surface of said tube;

25 a plug element attached to said hinge element, wherein said plug element is sized to close said passageway;

a protrusion extending from a distal side of said plug element to a distal end;

and

30 a bump extending from said inner surface of said tube, said bump defining a socket in said bump, wherein said distal end of said protrusion rests in said socket when said plug element closes said passageway, wherein when the pressure differential reaches the first predetermined value, the pressure differential causes said

plug element to swing toward the distal end of the tube and thereby causes said protrusion to snap over said bump, when said pressure differential reaches said second predetermined value, said elastic hinge element causes said plug element to swing up to close said passageway.

5 16. A device according to claim 7, wherein said valve assembly comprises means for sensing opening and closing of the pylorus, and wherein said valve assembly is adapted to open and close said passageway corresponding to the opening and closing of the pylorus.

10 17. A device according to claim 7, wherein said valve assembly comprises means for detecting digestive juices in a digestive tract of the patient, and wherein said valve assembly is adapted to open and close said passageway in response to the detected digestive juices.

15 18. A device according to claim 7, wherein said valve assembly comprises means for detecting hormones in a digestive tract of the patient, and wherein said valve assembly is adapted to open and close said passageway in response to the detected hormones.

19. A device according to claim 1, wherein said annular element is flexible.

20 20. A device according to claim 1, wherein at least a portion of said flexible tube is thin-walled and made of a flexible material such that the thin-walled portion collapses to a substantially flat condition when subjected to a positive pressure differential from the outside of the tube to the inside of the tube.

21. A device according to claim 1, wherein said flexible tube includes two sections, a first section connected to the relatively small inner boundary of said annular element, and a second section connected to a distal end of said first section, wherein said first section has a length such that when said device is attached to the inner wall of the stomach, said first section extends to the pylorus of said patient, wherein said second section is thin-walled and made of a flexible material such that

the second section collapses to a substantially flat condition when the pressure outside the second section is greater than the pressure inside the second section.

30 22. A device according to claim 21, wherein said first section is made of a flexible material such that when the pressure differential from the outside of the first section to

the inside the first section is greater than a predetermined value, said first section collapses to a substantially flat condition.

23. A device according to claim 21, wherein said first section is accordion-like shaped such that the length of said first section compresses and expands without substantial change to the diameter of said lumen within said first section.

24. A device according to claim 21, wherein said device comprising a first valve assembly disposed near the proximal end of said tube, and a second valve assembly disposed at the distal end of said first section, wherein said valve assemblies are adapted for opening and closing said passageway.

25. A device according to claim 1, wherein said flexible tube has a length of about 50 to 200 cm.

26. A device according to claim 1, wherein said flexible tube has a length such that when said device is attached to the stomach of the patient, said tube extends beyond the pylorus of said patient.

27. A device according to claim 1, wherein said relatively large outer boundary of said annular element is adapted to be attached to the inner wall of the stomach by sutures.

28. A device according to claim 1, wherein said relatively large outer boundary is adapted to be attached to the inner wall of the stomach by staples.

29. A device according to claim 1, wherein said relatively large outer boundary is adapted to be attached to the inner wall of the stomach by adhesive.

30. A device according to claim 1, wherein said relatively large outer boundary is adapted to be attached to the inner wall of the stomach by any combination of sutures, staples, and adhesive.

31. A device according to claim 1, wherein said annular element includes an annular flange extending from said relatively large outer boundary of said annular element, said annular flange is adapted to be attached to the inner wall of the stomach.

32. A device according to claim 31, wherein said flange is reinforced with a fibrous material.

33. A device according to claim 1, wherein said flexible tube is accordion-like shaped such that the length of said tube compresses and expands without substantial change to the diameter of said lumen within said flexible tube.

34. A device according to claim 1, wherein said annular element is adapted to be attached to the inner wall of an upper portion the stomach, which is close to the esophagus of the patient.

35. A device according to claim 1, wherein said relatively large outer boundary of said annular element has a diameter which is smaller than the diameter D of a portion of the stomach where the annular element is to be attached, such that when said annular element is attached to the inner wall of said portion, said portion of said stomach is constricted.

36. A device according to claim 1, wherein said tube comprises a flexible portion which passes through the pylorus of the patient such that when the pylorus constricts, said portion is compressed so that said passageway is closed by the pylorus.

37. A device according to claim 1, wherein said tube comprises a portion that passes through the pylorus of the patient, said portion comprising channels for conducting fluid from stomach to intestine.

38. A device according to claim 1, wherein said tube defines at least one one-way channel on a lateral wall of said tube, said one-way channel allowing passage of fluid from a digestive tract of said patient into said lumen and impeding passage of food from said lumen to said digestive tract.

39. A device according to claim 1, wherein said tube comprises two sections, a first section extending from said distal end of said annular element, and a second section, wherein said first section includes a flexible distal portion which diameter tapers to its distal end, and wherein said second section includes a trumpet-bell shaped proximal portion at a proximal end of said second section, and wherein said distal portion of said first section is inserted into said proximal portion of said second section and is connected to the second section by connecting means, forming an overlapping portion, said overlapping portion passing through the pylorus of the patient when the device is attached to the stomach, such that when the pressure inside

said overlapping portion is greater than the pressure outside the overlapping portion, walls of said flexible distal portion expands and in tight contact with walls of said proximal portion, and when the pylorus compresses said overlapping portion, said flexible distal portion of said first section collapses, creating at least one gap between

said distal portion and said proximal portion for conducting fluid from the pylorus-end chamber into the second section.

40. A device for treatment of obesity of a patient comprising:

an annular element having a relatively large outer boundary and a relatively

5 small inner boundary;

an elongated flexible tube extending between a proximal end and a distal end, said tube defining a central lumen within said tube, said proximal end of said tube being connected to said relatively small boundary of said annular element, and forming a continuous passageway through a region interior to said relatively small

10 boundary and said lumen,

wherein said relatively large outer boundary of said annular element is adapted to be attached to an inner wall of a stomach of said patient, such that said annular element divides said stomach into two chambers, an esophagus-end chamber close to an esophagus of said patient, and a pylorus-end chamber close to a pylorus of said patient, and wherein said esophagus-end chamber is in fluid communication with said

15 lumen of said tube,

wherein said flexible tube includes two connected sections, wherein said first section has a length such that when said device is attached to the inner wall of the stomach, said first section extends from the relatively small inner boundary of said annular element to the pylorus of said patient, wherein said second section is made of a flexible material and is thin-walled such that said second section collapses to a substantially flat condition when the pressure outside the second section is greater than the pressure inside the second section.

20 41. A device according to claim 40, wherein said device further comprises a valve assembly disposed within said passageway near said proximal end of said tube, wherein said valve assembly is adapted for opening and closing said passageway.

42. A device according to claim 40, wherein said valve assembly opens when a pressure differential from a proximal side of said valve assembly to a distal side of said valve assembly reaches a pressure differential created by swallowing, and

30 remains closed when the pressure differential across the valve assembly is less than the pressure differential created by swallowing.

43. A device according to claim 40, wherein said first section is accordion-like |
shaped such that the length of said first section compresses and expands without
substantial change to the diameter of said lumen within said first section.

44. A device for treatment of obesity of a patient comprising:

5 an annular element having a relatively large outer boundary and a relatively | ind.
small inner boundary;

wherein said relatively large outer boundary of said annular element is adapted
to be circumferentially attached to an inner circumference of a stomach of said
patient, such that said annular element divides said stomach into two chambers, an
10 esophagus-end chamber close to the esophagus of said patient, and a pylorus-end
chamber close to a pylorus of said patient.

45. A device according to claim 44, wherein said relatively large outer boundary |
of said annular element is adapted to be circumferentially attached to an inner
circumference which is at an upper portion of said stomach.

15 46. A device according to claim 44, wherein said relatively large outer boundary |
of said annular element has a diameter less than the diameter of the circumference of
the stomach on which said relatively large outer boundary is to be attached, such that
when said annular element is attached to said circumference, said stomach is
constricted.

20 47. A device according to claim 44, wherein said device is made of a biologically |
compatible material.

48. A method for treatment of obesity of a patient comprising:

inserting an annular element having a relatively large outer boundary and a
relatively small inner boundary into a stomach of the patient; and | ind.

25 attaching said relatively large outer boundary of said annular element to an
inner circumference of the stomach of said patient, such that said annular element
divides said stomach into two chambers, an esophagus-end chamber close to an
esophagus of said patient, and a pylorus-end chamber close to a pylorus of said
patient.

30 49. A method according to claim 48, wherein said inner circumference is at an
upper portion of said stomach which is close to the esophagus of said patient.

50. A method according to claim 48, wherein said annular element further comprising an elongated flexible tube extending from the relatively small inner boundary in a distal direction, and wherein said method further comprising placing said elongated tube in an intestine of said patient. (
